



American Lamb Council



American Sheep Industry Association, Inc.

www.sheepusa.org



American Wool Council

October 6, 1999

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket No. 99N-2151, 21 CFR Part 514 (New Animal Drug Applications; Sheep as a Minor Species)

We are commenting on behalf of the American Sheep Industry Association, Inc. (ASI). ASI is the national producer trade association representing approximately 68,000 producers through state affiliates and other organizations.

ASI appreciates the opportunity to comment on Docket No. 99N-2151 "New Animal Drug Applications; Sheep as a Minor Species". ASI is on record supporting the reclassification of sheep as a minor species with respect to all data requirements for new animal drug applications (NADAs). We have met and corresponded with representatives of FDA/CVM on many occasions to communicate our support for the reclassification of sheep. ASI supports all efforts to assure the safety and quality of sheep products and we believe that this proposed action is consistent with this goal.

Reclassifying sheep to a minor species should reduce costs and some of the more burdensome data collection requirements that deter drug sponsors from pursuing NADAs for sheep as is stated in the docket. ASI believes that this change will result in more therapeutic products labeled for sheep in the future which, in turn, will result in healthier animals and ultimately in a more profitable U.S. sheep industry.

ASI is aware that CVM has based the classification of sheep on consumption data in the past. We agree with the agency that the body of evidence regarding the similarity of cattle and sheep drug metabolism is an appropriate criterion for specie classification and that it is a more appropriate criterion than estimates of meat consumption. We commend CVM for taking a science-based approach to reclassifying sheep and for publishing this proposed rule to amend Section 514.1 (d) (1) (ii). We urge the agency to issue a final rule to reclassify sheep as a minor species for all NADA data collection requirements in an expeditious manner.

If we can be of any assistance to CVM in this or other matters, we will be delighted to do so.

Submitted by

Cindy Siddoway

Cindy Siddoway, President
American Sheep Industry Association

99N-2151

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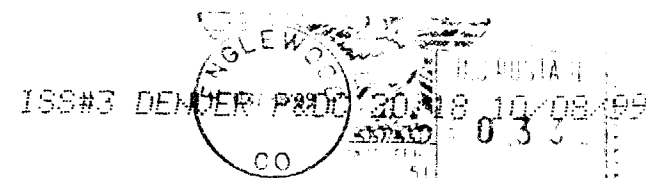


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